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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

THE PROIMMUNE COMPANY, LLC, a Delaware  
limited liability company;

Plaintiff,

v.

HOLISTA COLLTECH LTD., an Australian  
corporation; and DOES 1-50, inclusive;

Defendants.

Case No.: 7:20-cv-01247-KMK

**PLAINTIFF/COUNTERCLAIM-DEFENDANT THE PROIMMUNE COMPANY, LLC'S  
RESPONSE TO DEFENDANT/COUNTERCLAIM PLAINTIFF HOLISTA COLLTECH  
LTD.'S RULE 56.1 STATEMENT OF MATERIAL FACTS**

Pursuant to Federal Rules of Civil Procedure and Local Rule 56.1, Plaintiff/Counterclaim-Defendant The ProImmune Company, LLC (“ProImmune”) responds to Defendant/Counterclaim-Plaintiff Holista Colltech Ltd.’s Local Rule 56.1 Statement of Undisputed Material Facts (ECF # 46). ProImmune’s response is also subject to ProImmune’s objections to the evidence submitted by Holista, which are being filed concurrently.

1. ProImmune and Holista entered into several distribution agreements - a final one of which was entered into on September 1, 2018 (“Agreement”). Declaration of Rajen Manicka (“Rajen Dec.”) at ¶ 3 and Ex. A.; Declaration of Natraj S. Bhushan In Support (“Bhushan Dec.”) at Ex. 1 (Second Amended Answer with Counterclaims) at p. 8, ¶1 and Ex. 2 (ProImmune’s Reply) at p. 2 ¶1 (admitting that the Agreement was entered into).

#### **ProImmune’s Response**

1. Undisputed that the parties entered into a fourth distribution agreement (“Contract No. 4”) on September 1, 2018. Irrelevant and fails to raise an issue of material fact to the extent Holista’s counterclaim is only based on Contract No. 4.

Rajen Dec. at ¶ 3, Ex. A.

2. Pursuant to the express terms of the Agreement, and in reliance upon the Contractual Warranties and Certificate Warranties (as those terms are defined below), Holista paid approximately \$311,850.00 to ProImmune (through the course of three separate payments) for delivery of approximately three (3) tons of conforming Product. Rajen Dec. at ¶4 and Ex. B (Holista’s Verified Response to the Interrogatories).

**ProImmune's Response**

2. Undisputed that Holista paid \$311,850.00 over the course of three separate payments for Product according to the terms of Contract No. 4. Disputed to the extent Holista attempts to characterize its obligations or ProImmune's obligations, including but not limited to "delivery" and "conforming," outside of the clear language of Contract No. 4. Disputed to the extent Holista's purchases were not in accordance with the provisions of Contract No. 4 and were untimely, with the first payments being made in November 2018, when required to be made by August and September 2018.

Rajen Dec. at ¶ 3, Ex. A [Sections 1.1.11, 3.1, 3.6, 9, Schedules 1 and 3]; ¶ 4, Ex. B, p. 8.

3. Per the express terms of the 2018 Contract (e.g., §§ 4.1, 8.2, and 8.3) the Product to be delivered to Holista's Pick-Up's address was to conform to the specifications set forth in the Contract (e.g., §1.1.16 and item 2 of Schedule 1), which ProImmune warranted (§§9.1.1. (ii) and (iii), 9.1.2.) ("Contractual Warranties"). Rajen Dec. at ¶ 8 and Ex. A.

**ProImmune's Response**

3. Undisputed to the extent of the language contained in the cited provisions in Contract No. 4. Disputed to the extent Holista attempts to characterize its obligations or ProImmune's obligations outside of the clear language of Contract No. 4.

Rajen Dec. at ¶ 3, Ex. A [Sections 1.1.16, 4.1, 8.2, 8.3, 9.1.1(ii), 9.1.1(iii), 9.1.2, and Schedule 1].

4. Each shipped batch of Product to Holista was separately accompanied by a Certificate of Analysis ("Certificate Warranties"), which additionally warranted that the Product

within a shipped batch conformed to the exact specifications of ProImmune's Product's patent. Rajen Dec. at ¶ 9.

**ProImmune's Response**

4. Disputed. No batches of Product were "shipped" or otherwise obtained by Holista under Contract No. 4 because they failed to pick up Product when notified by ProImmune. Certificates of Analysis ("CofA") are not a warrantee but evidence of laboratory analysis that demonstrates the properties of Product.

Declaration of Albert Crum, M.D. ("Dr. Crum Dec.") ¶ 13; Rajen Dec. Ex. B, p. 8; Declaration of Stephen G. Chadwick ("Chadwick Dec.") ¶ 7, Ex. A

5. Prior to entering into this Agreement, Dr. Crum was well aware that Holista had its own customers (i.e., Qnet/ChakraWeCare) who were being reshipped the "as is" Product Holista had purchased from ProImmune. Rajen Dec. at ¶ 11 and Ex. B.

**ProImmune's Response**

5. Disputed. Holista shipped and repackaged the Product that it received from ProImmune. Also irrelevant and fails to raise an issue of material fact.

Declaration of Ryan Abbott ("Abbott Dec."), ¶ 2, Ex. A [11/23/20 Deposition of Dr. Rajen Manicka ("Dr. Rajen Depo. I")] at 41:1-10.

6. During the Term of the Agreement, Holista made three payments for \$311,850.00 to purchase Product, a small portion of which it picked up in reliance on these Express Warranties and then reshipped to its customers "as is." Nevertheless, it turned out that this Product was, in fact, non-conforming and a different Product altogether. Rajen Dec. at ¶ 13 and Ex. C.; *see also*,

Transcript of Dr. Albert Crum (“Crum Tr.”) at pp. 100-102, which is annexed as Exhibit 3 to the Bhushan Dec and Transcript of Nicholas Nash (“Nash Tr.”) at pp. 62-71, which it annexed as Exhibit 5 to the Bhushan Dec.

**ProImmune’s Response**

6. Disputed. The Product that Holista refers to was from Lot # 1015811, which had been shipped before the parties entered into Contract No. 4. The prior Product Holista received – Lot # 1015811 - also conformed exactly to the specifications and warranties of Contract No. 4. Irrelevant to the extent Holista’s complaints were regarding Product not related to Contract No. 4. Holista never picked up any Product purchased pursuant to Contract No. 4.

Dr. Crum Dec. ¶ 11, Ex. E; Abbott Dec. ¶ 3, Ex. B [12/1/20 Deposition of Dr. Rajen Manicka (“Dr. Rajen Depo. II”)] at 218:23-219:3, 221:18-22, 222:20-224:11, 225:17-23, 228:4-9; Chadwick Dec. ¶¶ 7-11, Ex. A.

7. ProImmune acknowledged that Holista paid for \$311,650.00 worth of Product, a “large portion” of which was never scheduled for pickup “because there were complaints.” Crum Tr. at pp. 87-88; 126-128; Rajen Dec. at Ex. B.

**ProImmune’s Response**

7. Disputed that Holista failed to receive the Product “because there were complaints.” ProImmune was obligated to deliver the Product to the “Pick-Up Address” and inform Holista that it was available for pick-up, which ProImmune did. Disputed that Holista paid for \$311,650.00 worth of Product. Holista paid \$311,850.00. Disputed that any of this Product was picked up.

Rajen Dec. at ¶ 3, Ex. A [Sections 1.1.11 and 3.6], ¶ 8, Ex. B at p. 8; Dr. Crum Dec. ¶ 13, Ex. F.

8. Throughout 2019, Holista outlined several material breaches of the parties Agreement, which included delivery of non-conforming Product (a breach of the Express Warranties); failure to ensure properly packed Product at the Pick-Up location; and defectively shipped goods. These breaches were communicated to ProImmune (usually by Dr. Rajen himself) through the course of emails or phone calls – several of which included copies of the test results showing the deficiency of the amino acid content of the Product. Rajen Dec. at ¶ 14 and Ex. C; Crum Tr. at pp. 90-92, 93-97, and 100-102; Nash Tr. at pp. 62-71.

### **ProImmune's Response**

8. Disputed. Exhibit C to the Declaration of Rajen Manicka is an email from 2017 and Contract No. 4 was not entered into until September 1, 2018. ProImmune was obligated to deliver the Product to the “Pick-Up Address” and inform Holista that it was available for pick-up, which ProImmune did. ProImmune had no obligations under Contract No. 4 regarding shipping. The contested batch of Product which was shipped under the parties’ third agreement conformed to all specifications and warranties as required. Irrelevant to the extent Holista’s complaints were regarding Product not related to Contract No. 4.

Rajen Dec. at ¶ 3, Ex. A [Sections 1.1.11, 3.6, 4.2, and 4.3], ¶ 8, Ex. B at p. 8; Dr. Crum Dec. ¶ 13, Ex. F; Abbott Dec. ¶¶ 2 and 3, Ex. A [Dr. Rajen Depo. II] at 137:21-23, and 139:20-25, Ex. B [Dr. Rajen Depo. II] at 218:23-219:3, 221:18-22, 222:20-224:11, 225:17-23, 228:4-9; Chadwick Dec. ¶¶ 7-11, Ex. A.

9. Dr. Crum had repeatedly promised Holista that he would honor any return of deficiently packed Product or Product that it was dissatisfied with. Rajen Dec. at ¶ 16; Crum Tr. at pp. 58, 71, and 77, 82-84, and 98.

**ProImmune's Response**

9. Disputed to the extent ProImmune had any obligations outside of the clear language of Contract No. 4. Disputed to the extent Holista failed to timely reject any Product under the terms of Contract No. 4. Disputed to the extent Holista failed to reject any Product at all.

Rajen Dec. at ¶ 3, Ex. A [Sections 1.1.1, 1.1.12, 4.1, 8.1, 8.2, and 8.3]; Abbott Dec. ¶¶ 2 and 3, Ex. A [Dr. Rajen Depo. I] at 134:9-13, and 136:10-14, Ex. B [Dr. Rajen Depo. II] at 184:2-9; Dr. Crum Dec. ¶¶ 5 and 12.

10. As to the defective Product delivered, a non-exhaustive list of the issues raised in this correspondence were the following: difference in texture, taste, color and amino acid content – each of which deviated from the 2018 Contract terms and were in breach of the Express Warranties. In fact, all of the foregoing was verified both by testing performed by Holista's customer and a separate independent analysis performed by an outside agent hired by Holista who each tested, unaltered Product and found it to be non-conforming. Rajen Dec. at ¶ 17 and Ex. C; Crum Tr. at pp. 100-103, 118-123.

**ProImmune's Response**

10. Disputed. Holista never possessed any Product under Contract No. 4 so it is impossible for there to have been problems that it became aware of regarding texture, taste, color, and amino acid content. ProImmune's obligations under Contract No. 4 were limited to color and mesh size. None of the evidence cited refers to any complaints regarding texture, taste, or color.

ProImmune confirmed that the contested batch – Lot # 1105811 – conformed exactly to the specifications and warranties that ProImmune was obligated to meet under Contract No. 4, which Holista admitted to in deposition.

Rajen Dec. at ¶ 3, Ex. A [Section 9, Schedule 1, paragraph 2]; Dr. Crum Dec. ¶¶ 4 and 10; ¶ 3, Abbott Decl. ¶ 3, Ex. B [Dr. Rajen Depo. II] at 218:23-219:3, 221:18-22, 222:20-224:11, 225:17-23, 228:4-9, and 236:22-237:7; Chadwick Dec. ¶¶ 7-11, Ex. A.

11. Holista made clear to ProImmune that its failure to deliver conforming Product or explain the discrepancies in Product consistency (with that which Holista was promised and already paid for) would result in further damages to Holista – namely, lost profits and damaged reputation in the form of cancellation of purchases of Product by Holista’s customers. Rajen Dec. at ¶ 18 and Ex. C; Nash Tr. at pp. 62-71.

#### **ProImmune’s Response**

11. Disputed. Immaterial and Irrelevant. Contract No. 4 precludes recovery for loss of profit, revenue, or consequential loss.

Rajen Dec. at ¶ 3, Ex. A [Section 13.6].

12. And when confronted with these material breaches and discrepancy in Product variation, neither ProImmune nor its manufacturer explained or justified the quality discrepancy despite numerous attempts from Holista. Rajen Dec. at ¶ 19; Crum Tr. 100-103, 118-123; Nash Tr. at pp. 62-71.



**ProImmune's Response**

12. Disputed. ProImmune specifically addressed the complaint regarding non-conforming Product, providing certificates of analysis for the final Product, each amino acid that comprised the final Product, and a stability test of the Product since the time it was manufactured. Holista admitted in deposition that ProImmune addressed the issues regarding non-conforming Product and that all Product was, in fact, conforming. ProImmune had no obligations as to shipping.

Dr. Crum Dec. ¶¶ 6-10, Exs. C and D; Abbott Decl. ¶¶ 2 and 3, Exs. A [Dr. Rajen Depo. I] at 137:21-23, 139:20-25; Ex. B [Dr. Rajen Depo. II] at 218:23-219:3, 221:18-22, 222:20-224:11, 225:17-23, 228:4-9; Chadwick Dec. ¶¶ 7-11, Ex. A; Rajen Dec. at ¶ 3, Ex. A [Section 3.6, 4.2, and 4.3].

13. The Product manufacturer (UST) and Mr. Nash ceased all communication with Holista in or around October 2019 and, Dr. Crum refused to get on the phone with Holista. As such Holista and its customers were left in the dark as to any viable explanation as to why the ProImmune amino acid content was so low and/or how ProImmune intended to cure the material breaches. Rajen Dec. at ¶ 20; Nash Tr. at pp. 62-71.

**ProImmune's Response**

13. Disputed. ProImmune specifically addressed the complaints regarding non-conforming Product, the Product was in fact conforming, and Holista admitted that all Product conformed to specifications as required in deposition.

Dr. Crum Dec. ¶¶ 6-10, Exs. A-D; Abbott Decl. ¶¶ 2 and 3, Ex. A [Dr. Rajen Depo. I] at 137:21-23, 139:20-25; Ex. B [Dr. Rajen Depo. II] at 218:23-219:3, 221:18-22, 222:20-224:11, 225:17-23, 228:4-9; Chadwick Dec. ¶¶ 7-11, Ex. A.

14. As a direct result of ProImmune's uncured breach of the Express Warranties, Holista ultimately had to pay a substantial sum of money to its customers (like Qnet) for failure to timely supply them with conforming Product, which Holista would have otherwise supplied but for the aforementioned breaches of ProImmune. Rajen Dec. at ¶ 23.

**ProImmune's Response**

14. Disputed. Irrelevant and Immaterial. Holista failed to timely purchase Product as required under Contract No. 4. Contract No. 4 also precludes any consequential damages.

Rajen Dec. at ¶ 3, Ex. A [Section 13.6, Schedule 3], ¶ 4, Ex. B at p. 8.

15. Rather than cure the material breaches outlines above, ProImmune ended up taking the "large portion" of Product that Holista paid for and sold it to non-party Three Aminos in March 2020. Crum Tr. at pp. 126-128; Bhushan Dec. at Ex. 4.

**ProImmune's Response**

15. Disputed to the extent ProImmune breached Contract No. 4. ProImmune delivered the Product to the Pick-Up Address and notified Holista that it was ready for Pick-up. Disputed that Holista picked up any of the above Product. Undisputed that ProImmune sold the Product to Three Aminos after Holista failed to pick it up.

Dr. Crum Dec. ¶¶ 13 and 14, Ex. F.

16. As a result of the foregoing, Holista has been damaged in an amount to be proven at trial, but estimated at no less than \$311,850.00 plus interest on its breach of contract claim as well as a sum to be determined at trial for ProImmune's breach of the Express Warranties. Rajen Dec. at ¶ 24.

**ProImmune's Response**

16. Disputed. ProImmune was obligated to deliver the Product to the Pick-Up Address and notify Holista that the Product was ready for pick up. It did both. Disputed that ProImmune has always been ready and willing to provide Holista with Product it paid for, should Holista desire to obtain the Product.

Dr. Crum Decl. ¶¶ 13 and 14, Ex. F.

**PROIMMUNE'S STATEMENT OF ADDITIONAL UNDISPUTED MATERIAL FACTS**

17. Holista had raised various complaints throughout the parties' relationship, which were primarily regarding shipping, and on two occasions, regarding the quality of the Product. All of these complaints dealt with Product that was obtained by Holista under the parties' first three contracts because Holista had never picked up Product under Contract No. 4.

Dr. Crum Dec. ¶¶ 4, 6, 11 and 13, Exs. E and F.

18. ProImmune had no obligations regarding shipping under Contract No. 4 or regarding the taste and texture of the Product. Holista admitted that it was responsible for shipping in deposition.

Rajen Dec. at ¶ 3, Ex. A [Sections 3.6, 4.2, 4.2, and Schedule 1, ¶ 2]; Ex. A [Dr. Rajen Depo. II] at 137:21-23, and 139:20-25.

19. Around August 2019, Holista notified ProImmune that its client QNet had tested batch 1015811 – a batch that Holista obtained under the parties’ third contract – and claimed that the amino acid content of the Product was 50% less than expected. Subsequently that same client had claimed that it retested that same batch of Product, and that it had tested at 88%.

Dr. Crum Dec. ¶¶ 6-10, Exs. A-D; Abbott Dec. ¶ 3, Ex. B [Dr. Rajen Depo. II] at 215:19-24, 218:23-219:3, 224:2-11.

20. UST’S testing demonstrates that Holista’s clients’ complaints were baseless. ProImmune provided Holista with certificates of analysis for both the finished Product and laboratory testing for all three amino acids that comprise the Product, as well as the results of a stability test. All tests demonstrated that the batch of Product at issue conformed to all specifications and warranties as required. Holista admitted that the Product conformed to the specifications as required in deposition, and that its only complaint was that ProImmune would not discuss the issues on the phone with them.

Dr. Crum Dec. ¶¶ 8 and 10, Ex C; Chadwick Dec. ¶¶ 6-12, Exs. A and B; Abbott Decl. ¶ 3, Ex. B [Dr. Rajen Depo. II] at 218:23-219:3, 221:18-22, 222:20-224:11, 225:17-23, 228:4-9, and 236:22-237:7.

21. ProImmune was obligated to deliver the Product to the Pick-Up Address and inform Holista that it was ready for pick-up. ProImmune did just that and Holista never picked up the Product.

Rajen Dec. at ¶ 3, Ex. A [Sections 1.1.11 and 3.6]; Dr. Crum Dec. ¶ 13, Ex. F.

22. Holista was obligated to purchase 12,000 kg of Product under Contract No. 4. Holista only paid for 3,500 kg of Product and did so late. Holist was obligated to purchase 2,500 kg by August 2018 and 1,500 kg by September 2018. Holista had not paid for any orders under Contract No. 4 until November 2018. Holista only paid for 3,500 kg of Product and did not make its complete payment until June 2019.

Rajen Dec. ¶¶ 3 and 6, Ex. A [Schedule 3], Ex. B.

23. Holista never rejected Product under Contract No. 4. Contract No. 4 had specific rejection requirements and Holista never once met them.

Rajen Dec. ¶ 3, Ex. A [Sections 1.1.1, 4.1, 8.1, 8.2, 8.3, Scheduled 2]; Abbott Dec. ¶¶ 2 and 3, Ex. A at 134:9-13, 136:10-14, Ex. B [Dr. Rajen Depo. II] at 184:2-9; Dr. Crum Dec. ¶ 5.

Dated: July 15, 2021

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**PROOF OF SERVICE**

I am a resident of the State of New York, over the age of eighteen years, and not a party to the within action. My business address is: Brown, Neri Smith & Khan LLP, 11601 Wilshire Blvd., Suite 2080, Los Angeles, CA 90025. On the date below, I served the document(s) as follows:

- **PLAINTIFF/COUNTERCLAIM-DEFENDANT THE PROIMMUNE COMPANY, LLC'S RESPONSE TO DEFENDANT/COUNTERCLAIM PLAINTIFF HOLISTA COLLTECH LTD.'S RULE 56.1 STATEMENT OF MATERIAL FACTS**

☒ **BY ELECTRONIC MAIL:** I caused such document(s) to be electronically mailed in PDF format as an e-mail attachment to each addressee for the above-entitled case. The transmission was complete and confirmed. A copy of the transmittal e-mail will be maintained with the original document(s) in our office.

To the addresses on the following address:

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Attorneys for Defendant/Counterclaim Plaintiff,  
Holista Colltech, Ltd.

I declare under penalty of perjury under the laws of the United States of America that the above is true and correct. Executed on July 15, 2021, at Albany, NY.



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